K010279

MAY 2 9 2001

Section I

510(k) Summary
Required by 21 CFR §807.92

I. Submitter:

A. Name: Medisystems Corporation

B. Address: 701 Pike Street, Suite 1600
Seattle, WA 98101-3016

C. Phone and Fax Numbers: Phone: (206) 834-1200
Fax: (206) 834-1201

D. Contact Persons: Ms. Karen Krstulich or Mr. Fred Swindler

II. Date of preparation of this Summary: 04/17/2001

III. Trade name: Medisystems Luer Access Injection Site

IV. Common name: Luer Access Injection Site

V. Classification name: Set, Administration, Intravascular

VI. The marketed device(s) to which equivalence is claimed: The Medisystems Luer Access Injection Sites are substantially equivalent to the Injection Site, Long with Luer Lock marketed by Baxter Healthcare Corporation.

VII. Product description: The device is a stand-alone injection site consisting of a plastic housing with elastomeric septum. The male Luer lock fitting on the housing allows the device to be attached to other compatible devices such as catheters. The device can then be used to allow access to the vascular system to administer fluids, take a blood sample, or as a heparin lock.

VIII. Statement of intended use compared to currently marketed predicate device: The proposed Medisystems Luer Access Injection Sites will be used with a vascular access device for fluid administration, blood sampling, or as a heparin lock. The Medisystems Luer Access Injection Sites can be connected to male Luer adaptors such as catheters to allow access to the vascular path. This is identical to the intended use of the legally marketed predicate device, Baxter Healthcare Corporation Injection Site, Long with Luer Lock. In addition, the Medisystems Luer Access Injection Site can be accessed by either metal hypodermic needles or Medisystems Medic® plastic anti-stick needles.

Attachment 2

MEDISYSTEMS

Luer Access Injection Site

Indications for Use: The Medisystems Luer Access Injection Site is indicated for use as an injection site attachable via a male luer connector to a vascular access device for fluid administration, blood sampling, or as a heparin lock. The Medisystems Luer Access Injection Sites can be connected to other compatible medical equipment such as catheters. The Medisystems Luer Access Injection Site can be used with either metal hypodermic needles or the Medisystems Medic® plastic anti-stick needle.

Contraindications: This device is not, in itself, a medical treatment device. Therefore, there are no absolute contraindications to its use. Use of the device is contraindicated if the features provided fail to meet the requirements consistent with the instructions for use of the blood access device.

Cautions and Warnings:

1. Federal (USA) law restricts this device to sale by or on the order of a physician.
2. Single use only – DO NOT REUSE.
3. Sterile, non-pyrogenic device if package is not damaged: This device has been sterilized by ethylene oxide.
4. Aseptic technique is required during use of this device.
5. Do not use more than a 1" (2.5 cm) needle to penetrate injection site.
6. Do not apply excessive internal pressure.

Directions for use:

1. Remove cap and, using aseptic technique, rotate clockwise to securely attach the injection site to the vascular access device.
2. Cleanse the surface of the injection site septum with appropriate antiseptic.
3. Fluids can be administered or withdrawn through the injection site septum using metal hypodermic needles or the Medisystems Medic® plastic anti-stick needle.
4. Follow facility's procedure for flushing.

Manufactured for:
MEDISYSTEMS
MEDISYSTEMS CORPORATION
SEATTLE, WA 98101-3016 USA

Made in Italy

QUESTIONS? COMMENTS?
CALL TOLL FREE
1-800-369-MEDI

INSXXX 01/2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2001

Ms. Karen Krstulich
Director of Regulatory Affairs
Medisystems Corporation
701 Pike Street, Suite 1600
Seattle, Washington 98101-3016

Re: K010279
Trade/Device Name: Medisystems Luer Access Injection Site
Regulation Number: 880.5440
Regulatory Class: II
Product Code: FPA
Dated: April 18, 2001
Received: April 19, 2001

Dear Ms. Krstulich:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section A

510(k) Number (if known): K010279

Device Name: Luer Access Injection Site

Indications For Use:

The proposed Medisystems Luer Access Injection Site will be used as an injection site attachable via a male luer connector to a vascular access device for fluid administration, blood sampling, or as a heparin lock. The Medisystems Luer Access Injection Sites can be connected to other compatible medical equipment such as catheters. The Medisystems Luer Access Injection Site can be used with either metal hypodermic needles or the Medisystems Medic® plastic anti-stick needle.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)

Vicki Hubbard for Pat Cicenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010279